



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Karen Leavy

From: Kevin Sweeney, Senior Entomologist

A handwritten signature in black ink, appearing to read "Kevin Sweeney", is positioned to the right of the "From:" line.

Date: September 27, 2011

Subject: Amended PRODUCT PERFORMANCE DATA EVALUATION RECORD

This DER amends the DER completed on September 20, 2011. The amendment is listed at the end of the review as "Amendment 1"

DP barcode: 389668

Decision no.: 446369

Submission no: 892428

Action code: A550

Product Name: EL2 One Pack

EPA Reg. No or File Symbol: 83997-O

Formulation Type: Wood Preservative

Ingredients statement from the label with PC codes included: 0.05% Imidacloprid (PC code 129099) and 2.5% 4,5-Dichloro-2-n-octyl-3(2H)-isothiazolone (PC code 128101)

Use pattern: wood preservative treatment for softwoods.

Application rate(s)/Retention rates of product/active ingredient:

For pressure treatment:

Treatment solution should contain 2.0%-4.8% of product by weight; equivalent to 500 ppm to 1200 ppm of each active ingredient (although the label does not state "each").

Retention rate following pressure treatment is 0.01-0.04 pounds of product per cubic foot of wood.

In an email communication dated September 19, 2011 the registrant claims to have submitted a label listing the range for product application to be 0.0125-0.065 pounds of product per cubic foot of EL2 active ingredient. I do not have this label. This language is the same as on one of the cited products – EPA Reg. No. 707-307.

OCSP Guideline: 810.3600

I. Action Requested: Review submitted studies and the label for the new product. The registrant cited additional data from a source Bayer imidacloprid based product and has authorization from them to cite the data.

II. Background: The registrant submitted one MRID containing multiple studies performed in accordance with American Wood Protection Association (AWPA) standards using formulations containing the same active ingredients and water repellent/stabilizer as the subject product. The registrant also cited three other studies that were previously reviewed by EPA in support of EPA Reg. No. 39967-15, which is the source product for imidacloprid in this formulation. EPA Reg. No. 707-307 was cited to support the fungicidal claims and rates.

III. Summary of MRIDs:

1. The non-GLP studies are acceptable. The registrant submitted summaries of the data. Original studies and data sheets were not provided.
2. Studies contained in **MRID 48414316** showed that the product performed effectively for up to 55 months in testing with softwood species against subterranean termites. Laboratory and field studies were performed with vacuum treated and untreated *Pinus* spp. including Southern Pine sapwood; Loblolly pine; and Radiata pine.
3. Water is used in these studies as a negative control and the testing included a water repellent/stabilizer mixed into the formulation. It appears that TBTO is used as a solvent.
4. Reviews of the cited studies: MRID44848102, MRID44848101, and MRID45133501, which were conducted with the source product, EPA Reg. No. 39967-15, are attached. The studies were found to be acceptable and supported the labeling for the source product.

MRID 48414316 Archer, K. 2011. EL2 One Pack Treated Wood: Summary of Available Termite Efficacy Data in Accordance with the American Wood Protection Association Standards and the Australasian Wood Preservation Committee Protocols.

Review

I. Study Summary – Laboratory Test Efficacy Data – Louisiana State University

Purpose: To determine the resistance of product treated wood to attack from the Formosan termite, *Coptotermes formosanus*.

Materials and Methods

No-choice (single choice) testing was performed in the laboratory using the AWPA E1 procedure. The procedure was attached to the study in Appendix A.

Test substance: DCOIT + imidacloprid only. Wood block samples were prepared by Rohm & Haas and provided to the Louisiana Forest Products Development Center. The wood blocks

measured 1 inch square by ¼ inch in the radial direction. A water repellent stabilizer was not included in the testing. Vacuum pressurized impregnation was used to treat the samples.

Test species: Formosan termite, *Coptotermes formosanus*. Life stage not stated but it is assumed to be the worker life stage.

Test design:

This was a no-choice test. There were two treatments - an untreated control and a product treatment. There were five wood blocks (5 replicates) in each treatment. The treated wood contained the test substance at 0.0187 pounds per cubic foot (pcf) (reported as 0.19), equivalent to 0.3kg/m³. Additional samples were provided for treated and untreated replicates for moisture determination.

An experimental replicate consisted of a sterilized glass testing jar containing 150 g of sand and 30mlof distilled water. The wooden test sample was placed on top of the sand. Four hundred wild termites were introduced into each jar, equivalent to 1.615 g of termite per jar.

The termites were exposed to the wood samples for 28 days. Matched moisture samples were compared and dry weight loss measured for the samples. Wood damage was also evaluated by the same rating system used by AWP and the USDA-Forest Service. Termite mortality was reported. Values were reported in table form.

Laboratory Results:

Test Substance	Formulation Retention – kg/m ³	Formulation Retention – pcf	Mean % Mortality	Mean %Wood Weight Loss	AWPA Rating
DCOIT + Imidacloprid ²	0.3	0.0187 ¹	99.4 ± 1.34	0.68 ± 0.31	10
Untreated control	0.0	0.0	16.1 ± 3.22	26.91 ± 4.68	1.7 ± 0.45

¹ Reported as 0.019 pcf

² The registrant reported (in an email dated 9/19/11) a dilution ratio of the active ingredients to be the same as the proposed product – 50:1, but I could not find that ratio stated in the study.

The mean mortality in the untreated control was 16.1% while the mean mortality in the treatments was 99.4%. Four of the five treated replicates had 100% mortality. Of greater significance were the wood damage ratings and weight loss values. In the treatments, only 0.68% weight loss was reported with virtually no termite damage to the wood (AWPA Rating = 10). In the untreated control, the termites caused a high degree of wood damage (AWPA Rating = 1.7), which resulted in a mean wood weight loss of 26.91%.

Conclusion from Laboratory Testing:

The subject product treatment, less water repellent/stabilizer, provided protection of the wood following a 28 day no-choice exposure when the formulation retention value was 0.0187 pcf.

II. Study Summary - Field Exposure Termite Tests

A. AWP A E26 Standard Field Test for Evaluation of Wood Preservatives Intended for Interior Applications [UC1 (interior dry)] and [UC2 (interior damp)]: Termite Ground Proximity Method.

Purpose: To evaluate the efficacy of the subject product as a wood preservative when treated wood is exposed to termites in an “interior setting” (as described below).

Experimental unit for all three field experiments:

Test samples were placed flat side down on top of open concrete block (wood was at least 50mm from the ground). Untreated “feeder” strips were placed between the blocks and in contact with the soil. These strips served as conduits for Formosan termite attack and directed them to the test samples on top of the block. The unit was covered with exterior plywood fastened above the unit in a manner to provide a slope for water drainage. The top and four side pieces were fastened to 1 x 6 pressure treated frame lumber to form a box, which kept the experimental unit dry. This experiment simulates a sill plate, shed or barn installation where wood is placed on concrete that is located on top of untreated soil. Construction type provides an opportunity for subterranean termite attack. This was a damp conditions exposure test (UC2) that could bridge to UC1 as well.

The AWP A rating system was used to assess wood damage. The test measured visual damage to the wood but did not report changes in the wood sample weight when compared to the control. The registrant did not express wood damage in terms of the AWP A scale. Instead they opted to convert the AWP A ratings to percentage values using a factor of 10 - with “10” representing 100% protection; 9 equaling 90% protection and so on. The percentage values were subjective because it is extremely difficult to visually grade damage from 9.5 to 10 on the AWP A scale. For consistency with data we review for termiticides from USDA-Forest Service testing I converted the percentage values to AWP A ratings. This did not change the outcome of the testing for registration purposes.

The criterion for success as defined by the AWP A is a 9.5 rating, equivalent to 95% protection. According to EPA Guidelines and AWP A recommendations the test should be run for at least 2 years and these field tests exceed that time period.

A1. Loblolly Pine Field Test in Hilo, HI USA

Materials and Methods:

Test substances/Treatments	Formulation Retention Rate - kg/m ³	Formulation Retention Rate -pcf
DCOIT + Imidacloprid (60:1 mixture)	0.29	0.0181
DCOIT + Imidacloprid (30:1 mixture)	0.30	0.0187
CCA treated wood	0.99	0.0618
Untreated	0.00	0.00

In this experiment the water repellent/stabilizer present in EL2 One pack was part of each of the mixtures. Water was used as a diluent. Wood was treated with the test substances using vacuum impregnation treatment (full cell) followed by a post treatment kiln drying.

Test species: resident (wild) Formosan termites (*Coptotermes formosanus*)

Replication: 10 replicates per treatment.

The test was conducted for 42 months.

Results (based on AWP Rating):

Termite feeding pressure was high as evidenced by the untreated control damage.

Test Substance	Formulation Retention Value -pcf	Formulation Performance (through 42 months)
DCOIT + Imidacloprid (60:1)	0.0181	9.5
DCOIT + Imidacloprid (30:1)	0.0187	9.5
CCA	0.0618	9.5
Untreated control	0.00	0-2

Conclusion:

The active ingredient ratios of 60:1 and 30:1 provided protection of wood against the Formosan subterranean termite through 42 months post-treatment and slightly outperformed the positive control substance. The 60:1 formulation retention value was 0.0181 pcf and the 30:1 formulation retention value was 0.0187 pcf.

A2. Ground Proximity Radiata Pine Field Test in Hilo, HI

The experimental protocol was the same as the Loblolly Pine test above except that the retention values were different. In this experiment the test substances were:

Test Substance	Formulation Retention Values - kg/m ³	Formulation Retention Values - pcf
DCOIT/Imidacloprid (60:1) + 0.3 pcf WR/Stabilizer	0.311	0.0194
DCOIT /Imidacloprid (30:1) + 0.3pcf WR/Stabilizer	0.311	0.0194
CCA	1.051	0.0656
Untreated control	0.00	0.00

Results (based on AWP rating):

Termite feeding pressure was high based on untreated ratings.

Test substance	Formulation Retention value-pcf	Formulation Performance (42 months)
DCOIT/Imidacloprid (60:1) + 0.3 pcf WR/Stabilizer	0.0194	9.5

DCOIT /Imidacloprid (30:1) + 0.3pcf WR/Stabilizer	0.0194	8.5-9.0
CCA	0.0656	9.0-9.5
Untreated control	0.00	0-1

Conclusion:

The 60:1 formulation provides protection against the Formosan subterranean termite through 42 months while the 30:1 formulation did not provide full protection through 42 months when applied to achieve formulation retention values of 0.0194 pcf. The 60:1 formulation outperformed the positive control.

III. Australasian Wood Preservation Committee Termite “Lunch Box” Test

The lunch box test was designed for evaluating termiticides and wood preservatives against mounding building termites but has been adapted for non-mounding subterranean species. The field test in Hilo, Hawaii for this purpose usually consists of placing the wood to be evaluated inside of plastic boxes with conduits to termite colony infestations. These infestations and lunch box placements are usually established in 55 gallon steel drums (but other structures have been used by some researchers). Based on the registrant’s description, I assumed that the standard method as described in the referenced protocol was employed in all three field tests. There were 10 replicates for each treatment.

a. Radiata Pine, Hilo HI USA

Test substances	Formulation Retention Value - kg/m ³	Formulation Retention Values - pcf
CCA (Type C)	2.979	0.174
TBTO (solvent)	0.093; 0.192; 0.440	0.0058, 0.0019, 0.0274
DCOIT + Imidacloprid + WR/Stabilizer ¹	0.087; 0.126; 0.232; 0.336	0.005, 0.0078, 0.0144, 0.0209
Water	0.00	0.00

¹ Registrant, in email dated 9/19/11 claims the ratio of actives is 100:1. I could not find any evidence of this in this submitted study. In section 3.2.1 the registrant mentions that this is EL2 One Pack treated wood, which leads me to believe that this is the subject product with an active ingredient ratio of 50:1. The low rate, 0.005 is one half the application rate recommended on the label.

Results (based on AWP rating):

Termite feeding pressure appears high throughout the field trial.

Test substances	Formulation Retention Values - pcf	Formulation Performance (55 months)
CCA (Type C)	0.174	9.5
TBTO (solvent)	0.0058, 0.0019, 0.0274	9.5-10
DCOIT + Imidacloprid + WR/Stabilizer ²	0.005, 0.0078, 0.0144, 0.0209	9.5-10
Water	0.00	0.0 ¹

¹ Water control was completely consumed by 12 months. No indication of replacement at 12 months to document termite pressure.

² The active ingredient ratio appears to be 50:1, which is the same as the subject product.

Conclusion:

The subject product (50:1 formulation) protected wood (Radiata pine) from Formosan subterranean termite attack through 55 months post-treatment at formulation retention rates as low as 0.005 pcf.

b. Lunch Box Test Loblolly Pine, Hilo, HI USA

Lunch box protocol as described above was used.

Test substances	Formulation Retention Values - kg/m ³	Formulation Retention Values-pcf
CCA	0.99	0.0618
DCOIT + Imidacloprid (30:1) + 0.3 pcf WR/Stabilizer	0.30	0.0187
DCOIT + Imidacloprid (60:1) + 0.3 pcf WR/Stabilizer	0.30	0.0187
Untreated	0.00	0.00

Results (based on AWP rating):

Termite feeding pressure was high during the field trial

Test substances	Formulation Retention Values-pcf	Formulation Performance (48 months)
CCA	0.0618	9.5
DCOIT + Imidacloprid (30:1) + 0.3 pcf WR/Stabilizer	0.0187	9.5
DCOIT + Imidacloprid (60:1) + 0.3 pcf WR/Stabilizer	0.0187	10
Untreated	0.00	less than 2

Conclusion:

The 30:1 and 60:1 formulations provided protection against Formosan subterranean termite attack at the retention value of 0.0187 pcf.

c. Lunch Box Test 2 with Radiata pine in Hilo, HI USA

The same protocol was employed as was described above.

Test substances	Formulation Retention Values - kg/m ³	Formula Retention Values -pcf
CCA	1.07	0.0667
DCOIT + Imidacloprid (30:1) + 0.3 pcf WR/Stabilizer	0.33	0.0206
DCOIT + Imidacloprid (60:1) + 0.3 pcf WR/Stabilizer	0.34	0.0212
Untreated	0.00	0.00

Results (based on AWP Rating):

Termite feeding pressure was high during the field trial

Test substances	Formulation Retention Values - pcf	Formulation Performance (48 Months)
CCA	0.0667	9.5
DCOIT + Imidacloprid (30:1) + 0.3 pcf WR/Stabilizer	0.0206	10

DCOIT + Imidacloprid (60:1) + 0.3 pcf WR/Stabilizer	0.0212	9.5
Untreated	0.00	0.0 ¹

¹ Untreated wood was consumed rapidly over time, declining from 1-2 rating at 37 months to 0 – complete consumption at 48 months.

Conclusion:

The 60:1 and 30:1 formulations protected wood from Formosan termite attack and performed as well as the positive control substance. The formulation retention value for the 30:1 formulation was 0.0206 pcf while the retention value for the 60:1 formulation was 0.0212 pcf.

Cited Data

The cited MRIDs (44848102, 44848101, and 45133501) were previously reviewed by the EPA in 1999 and 2000. The acceptance status of each is described below.

DER by G. Tompkins (see attached) dated July 29, 1999 under DP barcodes D257642 and D257645. These studies were rated “Supplemental”.

MRID 44848102 Preventol TM Preservative Insecticide and Preventol TM Insecticide (Efficacy): Lab Project Number 32/431; 32/430. 1995.

MRID 44848101 Termiticide Testing: Preventol TM Preservative Insecticide and Preventol TM Insecticide (Efficacy): Lab Project Number 5.1/5732 TE. 1991.

The two studies above were conducted according to European standards using Scots pine wood and the termite species, *Reticulitermes santonensis*, a species that causes damage to structures - predominantly in France. EPA considered these results in support of EPA Reg. Nos. 39967-15 and -17. The studies were rated “supplemental” and did not satisfy the product performance requirements. The registrant was instructed to conduct testing with U.S. species in the field as described in EPA guidelines.

DER by G. Tompkins (see attached) dated October 5, 2000 under DP barcodes D266658, D266636, D266633 and D26635 .

MRID 45133501 – Efficacy Data: Preventol TM (Imidacloprid). 2000. The data contained in this MRID included testing with *Reticulitermes flavipes* and *Coptotermes formosanus*.

This study was rated acceptable. Retention rates of imidacloprid ranging from 0.005-0.08 kg/m³ (0.0003-0.005 lbs per cubic foot) were found to be acceptable in the protection of wood for at least 2 years post-treatment.

IV. COMMENTS AND RECOMMENDATIONS:

1. The data are acceptable and support use against subterranean termites in the USA including the Formosan termite, *Coptotermes formosanus*, and economically important species from the genera *Reticulitermes*, *Heterotermes* and *Zootermopsis*.

2. The submitted studies satisfy AWPAC UC1 (interior dry) and UC 2 (interior damp) requirements. AWPAC UC3B (exterior above ground, uncoated or poor water runoff) also appears to be satisfied from the cited and submitted testing.
 - a. These recommendations are consistent with current AWPAC recommendations for DCOIT+ Imidacloprid with Stabilizer.
(<http://www.awpa.com/references/homeowner.asp>) AWPAC specifically recommends “EL2” - DCOIT + Imidacloprid +Stabilizer product retention rate of 0.019 pcf (0.0187 pcf), equivalent to 0.3 kg/m³.
 - b. The submitted and cited data are consistent with the AWPAC recommendation. Specifically, they support a product application rate of 0.0187 pcf with the recommendation/caveat that the minimum retention level for imidacloprid be stated as 0.0003 pcf. The registrant proposed a lower retention level but that would not be adequate to protect wood from termite attack.

I note that one of the “Lunch Box” tests provided evidence of efficacy at a lower rate (0.0001 lbs imidacloprid/cubic foot) but this was demonstrated in only one test. More data are required before a lower rate can be established and accepted for this use pattern.

3. Label language recommendations.
 - a. The registrant cited EPA Reg. Nos. 707-307 and 39967-15 and proposed language similar to that found on those labels.
 - b. I recommend that the following language be required on this label in the “Directions for Use” section of the label.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THE ENTIRE LABEL PRIOR TO USE. USE ONLY IN ACCORDANCE WITH LABEL PRECAUTIONS AND DIRECTIONS.

For use as a wood preservative to protect above ground treated wood from fungi, mold, mildew and subterranean termite attack (including the Formosan termite, *Coptotermes formosanus*, and species from the genera *Reticulitermes*, *Heterotermes* and *Zootermopsis*).

This is a water-borne wood preservative. Water shall be used as the diluent when dilution is required.

This product shall not be used as a wood preservative for ground or water contact. The product shall not be used for packaging food or feed or in the manufacturer of bee hives.

PRESSURE TREATMENT

For use in the pressure treatment of Southern pine and other treatable softwood lumber and

plywood for above ground applications such as decking, fencing, rails, spindles, flooring, trellises, and gazebos. Use 0.2% to 0.64% by weight (or 500ppm to 1200ppm a.i.) of product in the final treatment solution.

For millwork and joinery, trim and fascia, and sill plates use a 0.16% to 0.48% by weight (or 400 ppm to 1200ppm a.i.) of product in the final treatment solution.

Minimum required product retention level is 0.0187 pounds per cubic foot (pcf) for all treatments.

Note: this above product retention level is equivalent to 0.0003 lbs of imidacloprid per cubic foot of wood, which is the minimum retention level required for protection from subterranean attack.

Wood treatment procedures shall conform to the American Wood Protection Association (AWPA) Standards in place at the time of application. Wood treating cycles shall incorporate a post-treatment vacuum component equal to or greater than the initial vacuum step.

Post-Treatment Handling

Treated lumber and plywood shall be free from dripping before leaving the drip pad.

4. Addition of a dilution table.

The registrant should be advised to prepare a dilution table to prepare the treatment solutions. The table should include the %w/w values, ppm of each of the actives, and the amount of water to be add to make a 1000 gallon solution. The current text mentions ppm of "active ingredients" only and has no directions for how to prepare the solution.

5. Maximum retention levels. It isn't clear how the maximum retention values are arrived at. If the maximum values are restrictions due to human or environmental hazards, the restriction should be noted on the label.

Keuffner
9/27/11

Amendment #1 – This amendment addresses issues and discussions that took place after the completion of my DER dated September 20, 2011.

1. Registrant resubmission of labeling and response to comments.
 - a. The registrant revised the label in accordance with Agency comments including those made in review above. The registrant removed some of the requested language for millwork and joinery and included these applications with other pressure treatment applications. Second, the registrant proposed to remove the % concentration of the solution from the directions for use because so many different dilutions are possible when performing a pressure treatment of wood with this product. Instead, the registrant included the retention “rate” in the range of 0.015-0.004 pounds of product per cubic for EL2 active ingredients. **These changes are acceptable.**
 - i. (Note: for consistency the word “rate” should be changed to “level”.)
 - b. In response to Agency comments, the registrant added the minimum retention level of 0.0003 pcf for imidacloprid, which is required for protection of wood against subterranean termite attack. The registrant provided an “example solution preparation table” for the purpose of instructing the user on how to prepare a 1000 gallon end-use solution for pressure treatment of wood. The amount of product and the amount of water were listed to yield the 1000 gallon solution. The table expressed the level of DCOIT and imidacloprid in ppm. Note that smaller solution volumes yielding the same ppm of active ingredient are possible and legal. The same is the case for larger volume solution. **These changes are acceptable provided:**
 - i. “Solution Concentration” is changed to “Active Ingredient Concentration” in the solution preparation table.
 - ii. The concentration of each active ingredient (expressed in ppm) should be stated in the directions for use for each active ingredient in order to be in agreement with the table (500-1200 ppm for DCOIT and 10-24 ppm for imidacloprid).
 - c. **Add the word “termite”** to the last sentence of the pressure treatment section following the word “subterranean”.
2. I advise you that the cited product label, EPA Reg. No. 707-307, may have a solution preparation table that is incorrect.